IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

SUSAN SCHROCK, and STEVE SCHROCK,	)	
Plaintiffs,	)	
v.	)	Case No. CIV-08-453-M
PLIVA USA, INC., and QUALITEST PHARMACEUTICAL, INC.,	)	
Defendants.	)	

ORDER

Before the Court is plaintiffs' Motion for Leave to File Second Amended Complaint, filed October 27, 2011. On November 17, 2011, defendant Qualitest Pharmaceuticals, Inc. ("Qualitest") filed its response, and on November 28, 2011, plaintiffs filed their reply. Based upon the parties' submissions, the Court makes its determination.

I. Introduction

Qualitest was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and selling of Reglan/metoclopramide ("metoclopramide"). Qualitest submitted an Abbreviated New Drug Application to the Food and Drug Administration ("FDA"), requesting permission to manufacture, market, and distribute the generic metoclopramide.

Plaintiff alleges that Qualitest failed to investigate the accuracy of its metoclopramide drug labels and relied upon the name brand manufacture and listed drug companies to review the medical literature for its metoclopramide. Plaintiff further alleges that the package insert for the metoclopramide understated the risk of acute and long-term side effects of ingesting the drug. Qualitest and other manufactures advertised metoclopramide as a safe and effective treatment of

diabetic gastroparesis, gastrophageal reflux disease, and other gastrointestinal disorders.

In March 2000, plaintiff Susan Schrock's ("Susan") physician prescribed Susan metoclopramide to treat her reflux. According to plaintiffs, Susan's physician relied upon information published in the metoclopramide's package insert and/or the Physicians' Desk Reference or information otherwise disseminated by the Reference Listed Drug company and/or New Drug Application Holder. Plaintiffs allege that Susan ingested the metoclopramide as prescribed and that Susan's long-term ingestion of the drug caused her to suffer from tardive dystonia.[1]

On April 30, 2008, plaintiffs filed their Complaint. On February 8, 2011, the Court stayed the case at bar pending review by the United Stated Supreme Court in the matters of *Demahy v. Actavis*, *Inc.*, 593 F.3d 428 (5th Cir. 2010) certiorari granted no. 09-1501, and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), certiorari granted Nos. 09-993 and 09-1039. After granting certiorari, the Supreme Court consolidated the matters and issued its opinion styled as *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (hereafter, "*Mensing*"). Accordingly, on August 22, 2011, the Court lifted the stay in this matter.

II. Standard

The district court has discretion in deciding whether to grant leave to amend. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 330 (1971); *Foman v. Davis*, 371 U.S. 178, 182 (1963). However, a district court should grant leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). Thus, "district courts may withhold leave to amend only for reasons such as 'undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies

[1]Tardive dystonia is a debilitating neurological disorder characterized by involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk. There is no cure for tardive dystonia.

by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, or futility of the amendment.'" *United States ex rel. Ritchie v. Lockheed Martin Corp.*, 558 F.3d 1161, 1166 (10th Cir. 2009) (quoting *Foman*, 371 U.S. at 182). "A proposed amendment is futile if the complaint, as amended, would be subject to dismissal." *Anderson v. Merrill Lynch Pierce Fenner & Smith, Inc.*, 521 F.3d 1278, 1288 (10th Cir. 2008) (internal quotations omitted).

III. Discussion

A. Wyeth, Inc., Schwarz Pharma, Inc., Barr Pharmaceuticals, Inc., Actavis, Inc., and Actavis Elizabeth LLC

The caption of plaintiffs' proposed amendment includes previously terminated defendants Wyeth, Inc., Schwarz Pharma, Inc., Barr Pharmaceuticals, Inc., Actavis, Inc., and Actavis Elizabeth LLC.[2] Plaintiffs do not raise any new allegations against said defendants. To that end, plaintiffs' proposed amendment to include the previously terminated defendants would be futile because the claims against said defendants would be subject to dismissal on the same grounds as discussed in the Court's previous orders.

Therefore, the Court denies plaintiffs leave to amend as to include previously terminated defendants Wyeth, Inc., Schwarz Pharma, Inc., Barr Pharmaceuticals, Inc., Actavis, Inc., and Actavis Elizabeth LLC.

B. Negligence, Strict Liability, Gross Negligence, Misrepresentation, Fraud, and Punitive Damages

Qualitest asserts that plaintiffs seek to amend their complaint to include claims that the Court

[2] *See* the Court's March 11, 2009 Order [docket no. 101], Notice of Settlement with Actavis, Inc. and Actavis Elizabeth LLC [docket no. 177], Rule 41 Stipulation of Dismissal with Prejudice [docket no. 186].

previously found barred by the statute of limitations. Specifically, in the Court's July 20, 2010 Order, the Court found that the statute of limitations barred plaintiffs' recovery for negligence, strict liability, gross negligence, misrepresentation, fraud, and punitive damages. Plaintiffs' proposed amendment does not cure the complaint's failure to satisfy the statute of limitations. Thus, the Court finds plaintiffs' proposed amendment to include said claims would be futile due to plaintiffs' failure to satisfy the statute of limitations.

Therefore, the Court denies plaintiffs leave to amend as to include claims of negligence, strict liability, gross negligence, misrepresentation, fraud, and punitive damages.

C. Breach of Warranties

In *Mensing*, the Supreme Court concluded that federal drug regulations prevented generic manufacturers from independently changing their safety and efficacy labels. *Mensing*, at 2577. Further, the Supreme Court specifically held that federal drug regulations preempted a state law imposed duty to provide an adequate and safe warning label. *Id.* at 2581. The Supreme Court further opined:

> [W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.
>
> Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern.

Id. In light of the Supreme Court's decision in *Mensing*, plaintiffs' breach of warranties claim is preempted by federal drug regulations. The gravamen of plaintiffs' proposed breach of warranties claim alleges that "[d]efendants marketed and promoted their [metoclopramide] as safe and

efficacious for its intended uses . . . . Defendants expressly and impliedly warranted that the [metoclopramide] were not unreasonably dangerous and instead were merchantable and fit for its intended use . . . ." Second Amended Complaint [docket 317, Ex. 1], at ¶ 4.08. Based upon the *Mensing* decision, plaintiffs' breach of warranties claim is preempted because federal regulations bar Qualitest from independently changing its safety and efficacy labels; Qualitest's only independent action was asking for the FDA's help. Therefore, Qualitest could not satisfy its state law imposed duty for preemption purposes.

Accordingly, plaintiffs' proposed amendments to their breach of warranties claim are futile because federal drug regulations preempt said claim.

IV. Conclusion

For the reasons set forth above, the Court DENIES plaintiffs' Motion for Leave to File Second Amended Complaint [docket no. 317].

IT IS SO ORDERED this 8th day of December, 2011.

VICKI MILES-LaGRANGE
CHIEF UNITED STATES DISTRICT JUDGE